K111908(1/2)

BIOMET MICROFIXATION

NOV 29 2011

510(k) Summary

September 27, 2011

Contact: Biomet Microfixation
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Device Name: Biomet Microfixation Sternal Closure System **Common Name:** Plates and Screws

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Device Product Code: 87HRS (21 CFR 888.3030) **Device Classification:** Class II

Intended Use: The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation Sternal Closure System is intended for use in patients with normal and poor bone quality.

Description: Biomet Microfixation Sternal Closure System contains a variety of plates and 2.4mm and 2.7mm diameter self-drilling screws with maximum length of 20mm. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

Material: Titanium

Sterility Information: The Biomet Microfixation Sternal Closure System will be marketed as non-sterile, single use devices. Validated steam sterilization recommendations are included in the package insert.

Possible risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.
10. Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to the chest wall including vessels, pleura and other structures.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

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BIOMET MICROFIXATION

Substantial Equivalence: Biomet Microfixation considers the Biomet Microfixation Sternal Closure System to be equivalent to the Lorenz Sternal Closure System with Modular Screw (K011076), the Lorenz Sternal Closure System (K033740), the Lorenz Sternal Closure System (K063506) and the Biomet Microfixation Sternal Closure System (K110574) as well as Synthes Sternal Closure System (K093772), Synthes Zipfix (K110789), and Ethicon K931271 and K946173 Stainless Steel Suture Wire.

Characteristic	Device in this submission	Predicates: K011076, K033740, K063506, K110574	Predicates: Synthes K093772 and K110789	Ethicon - Stainless steel suture wire K931271 and K946173
Design	The Sternal Closure System includes the same plate and screw configurations contained in the predicate 510k's listed to the right.	Identical	K093772 Titanium plates and screws plates and screws K110789 (PEEK Optima LT-3) cable ties with detachable, stainless steel needle.	Stainless steel wire
Material	Plates: Titanium Screws: Titanium	Plates: Titanium Screws: Titanium	Plates: Titanium Screws: Titanium Zipfix: PEEK LT-3	316L Stainless steel
Size Range	Plates: various configurations Screws: 8mm to 20mm length	Plates: various configurations Screws: 8mm to 20mm length	unknown	Unknown
Indication	The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation Sternal Closure System is intended for use in patients with normal and poor bone quality.	The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures.	Intended for use in the primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.	Current standard of care for sternal closure applications – all bone types A nonabsorbable, sterile surgical suture composed of 316L stainless steel. Surgical stainless steel suture is available as a monofilament. Indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.
Non-Clinical Testing:				
Mechanical testing was performed to compare the Sternalock Blu Plating System to Stainless Steel surgical wire, for sternal closure. The testing was conducted using a polyurethane foam substrate which simulates Osteoporotic bone (see Patel Article, "Compressive properties of commercially available polyurethane foams as mechanical models for osteoporotic human cancellous bone") The mechanical testing showed that the Sternalock Blu Plating System had better performance compared to stainless steel surgical wire with respect to fatigue testing, shear force testing and lateral pull apart testing.				

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Microfixation
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Regulatory Affairs Manager
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Jacksonville, Florida 32218

NOV 29 2011

Re: K111908
Trade/Device Name: Biomet Microfixation Sternal Closure System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 27, 2011
Received: October 3, 2011

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111908 (1/1)

Indications for Use

510(k) Number (if known): K111908

Device Name: Biomet Microfixation Sternal Closure System

Indications For Use:

The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation Sternal Closure System is intended for use in patients with normal and poor bone quality.

Prescription Use _XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111908